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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,362	10/30/2003	Edward W. Merrill	00952-8081	6751
90628 7590 03/20/2012 Massachusetts General Hospital The General Hospital Corporation Perkins Cole LLP 700 13th Street, NW, Suite 600 Washington, DC 20005-3960				
EXAMINER BERMAN, SUSAN W				
ART UNIT		PAPER NUMBER		
1765				
NOTIFICATION DATE		DELIVERY MODE		
03/20/2012		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/696,362

Applicant(s)

MERRILL ET AL.

Examiner

/SUSAN W. BERMAN/

Art Unit

1765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-129 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-129 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB-08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

Response to Amendment

The rejection of claims 124-126 under 35 U.S.C. 112, second paragraph, is withdrawn.

The rejection of claims 124-126 under 35 U.S.C. 102(e) as being anticipated by Hyon et al is withdrawn. The process disclosed by Hyon et al does not comprise melting before irradiation.

The rejection of claims 124-126 under 35 U.S.C. 102(e) as being anticipated by Shen et al (6,228,900) is withdrawn. The process disclosed by Shen et al does not comprise melting before irradiation.

Response to Arguments

Applicant's arguments filed 01-18-2012 have been fully considered but they are not persuasive. See the previous discussions of these issues in the Office Actions mailed 1/14/2007, 09-07-2007, 12-12-2006, 07-24-2008, 09-14-2009, 03-15-2010 and 07-18-2011.

With respect to the rejection of claims 124-129 under USC 112, first paragraph: Applicant points to the disclosure at page 30 in the specification and in original claims 99 and 106 to support the claim recitation of a temperature of “about 230⁰C to about 300⁰C” in claims 124 and 127. Applicant’s argument is unpersuasive for the following reasons. The discussion at page 30 in the Specification provides support for a method wherein UHMWPE is melted and then irradiated and the temperature is “about 145⁰C to about 230⁰C”. Original claim 99 recites steps comprising heating UHMWPE to a temperature above the melting point and irradiating the heated UHMWPE and original claim 106 recites that the heating is at a temperature of “about 145⁰C to about 230⁰C”. These original claim recitations do not support the recitation in instant

claim 124 of heating at a temperature of “about 230⁰C to about 300⁰C”. These original claim recitations do not support the method steps set forth in instant claim 127 wherein the UHMWPE is irradiated and then heated to a temperature of “about 230⁰C to about 300⁰C”. The rejection is maintained.

Rejection of claims 127-129 over Shen et al ‘900: AS discussed previously, applicant’s priority date with respect to the method steps set forth in claims 127-129 is the 10-02-1996 effective filing date of Application US Serial No. 08/726,313. Applicant’s argument that the term “remelting” used by Shen et al is not found in the instant claims is unpersuasive for the following reasons. The cited disclosure of remelting is not irrelevant because Shen et al define remelting as heating the irradiated UHMWPE to a temperature above the melting point. Heating irradiated UHMWPE to a temperature above the melting point is what is set forth in instant claim 127. The difference is that claim 127 sets forth a temperature range; however, the temperature range is also taught by the disclosure of Shen et al. What Shen et al disclose is remelting “at a temperature from about 100⁰C to about 160⁰C above the melting temperature of the irradiated polymer...”.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 124-129 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner has not found any description of a process comprising heating an UHMWPE preform to a temperature “of about 230⁰C to about 300⁰C”. Applicant discloses heating at a temperature “of about 137⁰C to about 300⁰C, more preferably about 140⁰C to about 300⁰C, more preferably yet about 140⁰C to about 190⁰C, more preferably yet about 145⁰C to about 190⁰C, and most preferably about 150⁰C” in paragraph [0058] of PrePub 2004/0132856. A temperature “of about 230⁰C” is not mentioned. None of the Examples discloses a temperature of about 230⁰C.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

It is noted that amended **claims 124-126**, considered wherein the preform is irradiated subsequent to heating **are entitled to the 02-13-1996 filing date of US 5,879,400** because this parent patent discloses the method of melt irradiation (MIR).

It is noted that amended **claims 127-129** set forth the IR-SM (irradiation and subsequent melting) processes first disclosed in SN 08/726,313, but not disclosed in US '400. Therefore, the **effective filing date for instant claims 127-129 is considered to be 10-02-1996**, the filing date of application SN 08/726,313, which discloses WIR-SM and CIR-SM methods.

Claims 124-126 are rejected under 35 U.S.C. 102(b) as being anticipated by Gielenz et al, in the article “Crystalline and supermolecular structures in linear polyethylene irradiated with fast electrons”. Gielenz et al disclose a process for crosslinking polyethylene by irradiation in the molten state or in the solid state. See page 743. Before melting and

irradiation the polyethylene was formed into test bars, thus meeting the instant claim requirement for an UHMEPW preform. Radiation doses up to 150 Mrad were employed (Results 3.1 and Figures 2-4).

Claims 127-129 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626, having an effective filing date of May 06, 1996). Hyon et al disclose a method for producing UHMWPE for an artificial joint comprising irradiating UHMWPE with a low dose of radiation followed by compression-deformation after melting at a high temperature around the melting point and then cooling and solidifying. Hyon et al teach a process employing a temperature from the melting point minus 50⁰C to the melting point plus 80⁰C, which teaches temperatures within the range of 230⁰C to 300⁰C set forth in the claims. Table 2 appears to show that the samples treated according to the disclosed process have an increased tensile strength and an increased Young's modulus. With respect to claim 128, Hyon et al disclose temperatures around or not less than the melting point, preferably 160-220 ⁰C, that suggest the instantly recited temperature "about 230⁰C" (column 4, lines 4-16). Thus the process disclosed by Hyon et al anticipates the process of instant claim 128 wherein the heating step is about 230⁰C, a temperature "around or not less than the melting point", as taught by Hyon et al. With respect to claim 129, Hyon et al teach a preferable dose 0.01 to 5.0 MR (column 3, lines 62-65). Thus the process disclosed by Hyon et al anticipates the process of instant claim 129 wherein the gamma radiation dose is about 1 Mrad to 5.0 Mrad.

Claims 127-129 are rejected under 35 U.S.C. 102(e) as being anticipated by Shen et al (6,228,900, having an effective filing date of July 09, 1996). Shen et al disclose a process comprising irradiating preformed UHMWPE and remelting the irradiated UHMWPE in order to

enhance the wear-resistance of polymers and in vivo implants obtained from the polymers (column 4, lines 8-18, and lines 46-51, and column 6, lines 43-49). Shen discloses radiation doses from about 1 to about 100 Mrad (column 7, lines 20-31). The irradiated polymer is remelted at a temperature from **about 100⁰C to about 160⁰C above the melting temperature of the irradiated polymer, preferably from about 136⁰C to about 300⁰C** (column 7, line 53, to column 8, line 3). Thus, Shen et al disclose the instantly claimed process wherein preformed UHMWPE is irradiated at a dose of at least 1 Mrad and remelted at a temperature of about 230⁰C to about 300⁰C within the temperature range from about 136⁰C to about 300⁰C taught by Shen et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-126 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124, 126-129, 135-137 of copending parent Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point to

about 300°C and the time period is from about 5 minutes to about 3 hours or a time period of 5 minutes to about 24 hours and the polyethylene is UHMWPE. The processes set forth in the dependent claims also overlap with respect to temperature, radiation dose and intended properties. Thus the limitations of the process set forth in the instant claims are obvious variants of the limitations set forth in the claims of A.N. 10/197209.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 127-129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-125, 130 and 143-149 of copending parent Application No. 09/764,445. Although the conflicting claims are not identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point and below the decomposition temperature for a time period from about 5 minutes to about 3 hours. The processes set forth in the dependent claims also overlap with respect to temperature, radiation dose and intended properties. The polyethylene recited in the claims of A.N. '445 encompasses the UHMWPE recited in the instant claims. Claims 124, 125 and 130 suggest instant claim 127. Claim 143 suggests instant claim 124. Thus species within the instant claims are obvious from the limitations set forth in the claims of A.N. 09/764,445.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /SUSAN W. BERMAN/ whose telephone number is (571)272-1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
3/12/2012

/SUSAN W BERMAN/
Primary Examiner, Art Unit 1765